

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 011217US1			
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on _____</p> <p>Signature _____</p> <p>Typed or printed name _____</p>		Application Number 10/535,597	Filed 4/11/2006		
		First Named Inventor DENYER et al.			
		Art Unit 3771	Examiner STUART, Colin W.		
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table style="width: 100%; border: none;"><tr><td style="width: 50%; vertical-align: top; padding-bottom: 10px;"><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input checked="" type="checkbox"/> attorney or agent of record. 44,256 Registration number _____</p><p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p></td><td style="width: 50%; vertical-align: top; padding-bottom: 10px;"><p style="text-align: center;">/Timothy A. Nathan/</p><hr/><p style="text-align: center;">Signature</p><p style="text-align: center;">Timothy A. Nathan</p><hr/><p style="text-align: center;">Typed or printed name</p><p style="text-align: center;">724.387.4435</p><hr/><p style="text-align: center;">Telephone number</p><p style="text-align: center;">March 22, 2010</p><hr/><p style="text-align: center;">Date</p></td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>				<p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. 44,256 Registration number _____</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>	<p style="text-align: center;">/Timothy A. Nathan/</p> <hr/> <p style="text-align: center;">Signature</p> <p style="text-align: center;">Timothy A. Nathan</p> <hr/> <p style="text-align: center;">Typed or printed name</p> <p style="text-align: center;">724.387.4435</p> <hr/> <p style="text-align: center;">Telephone number</p> <p style="text-align: center;">March 22, 2010</p> <hr/> <p style="text-align: center;">Date</p>
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<p><input type="checkbox"/> *Total of _____ forms are submitted.</p>					

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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REASONS FOR PRE-APPEAL REQUEST FOR REVIEW

Indefiniteness Rejection

Claims 1-20 and 27 were rejected as indefinite because “it is not known whether the claimed method steps [in claim 1] are performed by structure such as a controller/microprocessor or mentally by a doctor or other medical technician present.” 12/22/09 Office Action, ¶ 2. Claim 1 does not and need not specify who or what performs the claimed steps. Unless otherwise recited, the method steps can be performed by any structure or person. Breadth is not indefiniteness. The Office Action’s recognition that these steps could be performed by “a controller/microprocessor or” a person confirms the definiteness of claim 1. Applicants therefore respectfully request the reversal of this indefiniteness rejection.

Obviousness Rejection Over Edgar

Claims 21 and 23-25 were rejected as obvious over Edgar (U.S. Patent No. 4,677,975). The rejection proposes no modification to Edgar, much less an obvious rationale for such an unidentified modification. 12/22/09 Office Action, ¶ 4. This obviousness rejection should be reversed as improper for this reason alone. If it is in fact an anticipation rejection, Applicants traverse it because Edgar clearly lacks at least two recitations in independent claim 21.

First, claim 21 recites, among other things, a “controller ... configured to ... detect, via the airflow sensor, a time the person takes to stop inhaling after being signaled.” Edgar discloses the ceasing of inhale signals to the patient (alleged by the Office Action to be the recited “signal to the person to cease inhalation”). *See* Edgar, col. 3, lines 13-14 (“the inhale signals at 24 are turned off”). Edgar also discloses sensing the start of exhalation (alleged by the Office Action to be the detection of the stop of inhalation). *See* Edgar, col. 3, line 17 (“the start of exhalation is detected”). However, Edgar does not disclose detecting a length of time between those two events, i.e., “a time the person takes to stop inhaling after being signaled,” as recited in claim 21. Such a time is irrelevant to the operation of Edgar’s device. Moreover, Edgar is not able to detect this irrelevant length of time because Edgar includes no structure capable of detecting the time difference between the two events (the stop of an inhalation signal and the start of exhalation).

Second, claim 21 recites, among other things, that “the controller is configured to ... adjust the pre-set period of time for subsequent inhalations depending on the detected time the person takes to stop inhaling after being signaled.” Because Edgar does not detect this “detected

time,” as explained above, Edgar does not disclose adjustment of the pre-set period of time based on a non-existent “detected time.” Indeed, Edgar discloses no ability to adjust the pre-set period of time, much less a controller that adjusts such a pre-set time period “depending on the detected time the person takes to stop inhaling after being signaled,” as recited in claim 21.

The Office Action responds to the above argument by asserting that Edgar’s apparatus is “capable of adjusting a pre-set inhalation time.” 12/22/09 Office Action, p. 9, ¶ 10. Applicants specifically traverse this assertion because Edgar includes no such disclosure. The Office Action’s cited passage from Edgar merely states that its “compressed air nebulizer is... able to be switched on and off and the intermittent nature of the operation allows selection of the running period to achieve a desired result.” Edgar, col. 3, lines 24-27. The selection of a “running period” involves the total running time of the apparatus for a desired dose, which includes numerous breaths. *See* Edgar, col. 2, lines 44-65. Such a running period has nothing to do with a “pre-set inhalation time,” which involves a single inhalation. Furthermore, even if Edgar’s adjustment of the “running period” were incorrectly deemed an adjustment of the “pre-set inhalation time,” such adjustment still would not “depend[] on the detected time the person takes to stop inhaling after being signaled,” as recited in claim 21.

For at least these reasons, Applicants request the reversal of this rejection of claim 21, as well as its dependent claims, which are allowable at least because they depend from claim 21.

Obviousness Rejection Over Schuster in view of Mishelevich and Crockford

Claims 1-12, 18-20, and 27 were rejected as obvious over Schuster (U.S. Patent No. 5,906,202) in view of Mishelevich (U.S. Patent No. 5,363,842) and Crockford (U.S. Patent Application Publication No. 2003/0205229). Applicants respectfully traverse this rejection because the proposed combination clearly lacks at least three different recitations in claim 1.

First, claim 1 recites, among other things, “detecting a time the person takes to stop inhaling after being signaled.” None of the cited references, either individually or in combination, disclose such a combination of recitations. Schuster discloses “prompt[ing] the patient to stop the inhalation,” but does not disclose the detection of how long it takes the patient to comply. Schuster, col. 2, line 63. Mishelevich and Crockford are similarly deficient.

The Office Action responds to this argument by asserting that:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Schuster to include the steps of detecting a pre-set time duration of inhalation and comparison to target envelope as taught by Mishelevich in order to ascertain a more accurate description of a patient's breathing pattern.

12/22/09 Office Action, p. 4 (underlining added). Even if true, the Office Action admits that the resulting combination would merely measure a “pre-set time duration of inhalation” as a whole. Measurement of the duration of the entire inhalation is not a measurement of “a time the person takes to stop inhaling after being signaled” to stop inhalation, as recited in claim 1.

The Office Action next asserts that “[t]he modified Schuster's device also discloses the ability of the microprocessor to detect a time the person takes to stop inhaling after being signaled (col. 13, ln. 34-36).” 12/22/09 Office Action, p. 4 Applicants traverse this assertion because the cited passage includes no such teaching, and rather merely states that “[t]he recorded information is analyzed by the microprocessor in order to deduce the timing and volume of aerosol and particle free air to be released into the patient's inspiratory cycle.” Schuster, col. 13, lines 34-36. This passage does not disclose or render obvious “detecting a time the person takes to stop inhaling after being signaled,” as recited in claim 1.

The Office Action responds to Applicants' above argument by asserting that the proposed combination “contains structure such that it is capable of detecting the time as claimed.” 12/22/09 Office Action, p. 10 (underlining added); *see also id.* at p. 4. Even if correct, the ability/capability of a structure to be used in a manner recited in method claim 1 clearly falls short of a disclosure to actually so use the structure. The Office Action has not alleged, must less demonstrated that it would have been obvious to use the proposed combined structure to “detect[] a time the person takes to stop inhaling after being signaled,” as recited in method claim 1. The rejection must be reversed because it provides no rationale, much less an obvious rationale, to use the prior art structure in the manner claimed in method claim 1.

Second, claim 1 recites, among other things, “adjusting the pre-set period of time for subsequent inhalations.” The Office Action concedes that Schuster lacks such a teaching. The Office Action similarly concedes that modifying Schuster in view of Mishelevich likewise lacks

such a teaching because Mishelevich merely discloses “direct[ing] the patient to change breathing pattern to match the pre-set time period instead of changing the pre-set time period.” 12/22/09 Office Action, p. 4. The Office Action asserts that Crockford would have made it obvious to have adjusted the pre-set period of time “in order to accommodate to a patient’s breathing pattern who may have respiratory problems and cannot change their breathing pattern” based on Crockford’s alleged disclosure of “adjust[ing] subsequent breathing patterns to match the patient’s needs (Crockford para. 0056 ln. 9-15).” 12/22/09 Office Action, pp. 4-5. To the contrary, Crockford has no such teaching. Crockford does not teach adjusting the patient’s breathing pattern at all, and is merely directed toward adjusting internal workings of the drug delivery device itself. The cited passage from Crockford merely discloses changing the timing of atomization within the device so as to occur “during a part of the inhalation of the patient.” Crockford, ¶ [0056]. Such internal workings of Crockford’s device have nothing to do with changes to how Crockford’s device instructs the patient to breath. Thus, Crockford does not make it obvious to “adjust[] the pre-set period of time for subsequent inhalations,” wherein the pre-set period is used to “signal[] to the person to cease inhalation,” as recited in claim 1.

The Office Action responds by asserting that the proposed combination of prior art is “capable of adjusting based on the time periods.” 12/22/09 Office Action, p. 10 (underlining added). Again, the ability/capability of a structure to be used in a manner recited in method claim 1 is not the same as a disclosure to actually so use the structure. The rejection must be reversed because the Office Action fails to provide any reason, much less an obvious reason, to have actually used the prior art structure in the manner claimed in claim 1, specifically to “adjust[] the pre-set period of time for subsequent inhalations.”

Third, claim 1 recites, among other things, “adjusting the pre-set period of time for subsequent inhalations depending on the time the person takes to stop inhaling after being signaled.” None of the cited references, nor their combination, disclose such a combination of recitations because, as explained above, they do not even render obvious the detection of such a “time the person takes to stop inhaling after being signaled.” The cited references cannot render obvious using a non-disclosed, non-obvious “time the person takes to stop inhaling after being

signaled” as the basis for “adjusting the pre-set period of time,” as recited in claim 1.

The Office Action asserts that the combination would render it obvious “to adjust[] the pre-set time...in order to accommodate to a patient’s breathing pattern who may have respiratory problems and cannot change their breathing pattern.” 12/22/09 Office Action at 4-5. Even if such an assertion were correct (Applicants dispute this as explained above), Applicants specifically traverse the Office Action’s further assertion that such accommodation for the patient’s respiratory problems/breathing cycle “would depend on the time the person takes to stop inhaling after the signaled [sic] to stop as comparison to target envelopes.” 12/22/09 Office Action, p. 5. Quite to the contrary, adjustment to accommodate for the specific breathing cycle of a patient does not necessarily or obviously depend on the time the person takes to stop inhaling after any signal to stop inhalation is given. A patient’s respiratory-problem-based breathing cycle has nothing to do with a lag between when the patient is signaled to stop inhalation and when the patient actually does so. Thus, none of the references, nor their combination disclose or otherwise render it obvious to adjust the pre-set time based on a patient’s compliance lag, i.e., “the time the person takes to stop inhaling after being signaled.”

For at least these reasons, Applicants request the reversal of this rejection of claim 1, as well as its dependent claims, which are allowable at least because they depend from claim 1.

Obviousness Rejections of Dependent Claims

Various dependent claims were rejected over various combinations of prior art. Applicants respectfully traverse these rejections at least because these claims depend from non-obvious independent claims. The additionally cited prior art does not cure the deficiencies with respect to the independent claims. Nor does the Final Office Action allege that they do. Applicants therefore respectfully request the withdrawal of these obviousness rejections.